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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,231	03/25/2004	Mary Jo. A. Toomey	7056 US (1)	9460
55748 7590 02/07/2008 TYCO HEALTHCARE GROUP LP 15 HAMPSHIRE STREET MANSFIELD, MA 02048			EXAMINER CHAPMAN, GINGER T	
			ART UNIT 3761	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/810,231

Applicant(s)

TOOMEY ET AL.

Examiner

Ginger T. Chapman

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3761

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 and 43-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 50-52 is/are allowed.
- 6) ☒ Claim(s) 1-12 and 46 is/are rejected.
- 7) ☒ Claim(s) 43-45 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 September 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

DETAILED ACTION

Status of the claims

1. Claims 47-52 are added; claims 1-7, 9-12 and 43-52 are pending in the application.

Claim Rejections - 35 USC § 103

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1-12 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328).
3. With respect to claims 1 and 46, in Figures 1, 7 and 8, Grossman teaches a fluid collection apparatus (fig. 3) comprising: a housing (11) configured for receipt of fluid and having a first surface which defines a mating portion including a needle and a blood port in the form of a poppet valve (40); a holder (16) having a first end and a second end (fig. 4) configured to receive an evacuated tube (30), the first end (17b) defining a second mating portion (40) on an outer surface thereof (43) which is in fluid communication (45) with the evacuated tube (30), the first mating portion (17b) adapted to releasably couple and sealingly engage the second mating portion (40) (c. 4, ll. 25-43) to establish fluid communication therebetween; and a base (13) disposed within the housing.
4. Grossman teaches the claimed invention except for a needleless first mating portion, except for a base being positionable on a support surface to support the holder and the housing in upstanding relation with respect to the support surface, and except for first and second connectors.

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5. The examiner notes that claims 1 and 46 recited the base being positionable on a support surface to support the holder and the housing in upstanding relation with respect to the support surface. The base of Grossman is fully capable of supporting the holder and housing in upstanding relationship only when the evacuated tube for collecting fluid is excluded from the apparatus. That is, the apparatus of Grossman would destroy or break a tube if a user attempted to stand the Grossman device on a flat surface with the tube in place. However, the examiner notes that the claimed evacuated tube is only **inferentially included** in claims 1 and 46. That is, the tube is not required, and, so long as the apparatus of Grossman is not in use conditions, i.e. is not being used to collect fluids and has no tube received in the holder, the apparatus is fully capable of being positionable on a support surface and supporting the holder and housing in upstanding relation.

6. Grossman fails to teach first and second connectors to releasably mount the holder to the housing; however it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlichman*, 168 USPQ 177, 179.

7. Grossman fails to teach the first mating portion is needleless, however, in an embodiment wherein the holder receives a syringe, the housing comprises a needle-less first mating portion port which is actuated by a syringe, and the syringe needle cannula comprises a second mating portion, permitting blood to flow therebetween. Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to form the first portion of Grossman without a needle since it has been held that rearranging parts of an invention requires only routine skill in the art. *In re Japikse*, 96 UPSQ 70.

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8. With regard to claim 2, as best depicted in Figure 2, Grossman et al disclose the base (13) has a top opening adapted for receiving the housing (15, 11).

9. With regard to claim 3, as best depicted in Figure 2, Grossman et al disclose the base (13) is adapted for standing on a surface (c. 3, ll. 8-9).

10. With regard to claim 4, as best depicted in Figures 2 and 4, Grossman et al disclose the base (13) is configured to enclose holder (16).

11. With regard to claim 5, Grossman et al disclose the housing (11) has a flange portion (43) extending radially therefrom that engages the base (15).

12. With regard to claims 6 and 7, Grossman et al disclose at least one rib (19) and a plurality of ribs (19).

13. With regard to claims 10 and 11, Grossman et al disclose a removable cap (22) adapted to removably enclose an opening of the housing (11) and provides a fluid seal within housing.

14. With respect to claim 47, as depicted in Figure 3, Grossman teaches the holder includes an internal access cannula for accessing the evacuated tube and directing fluid into the evacuated tube received within the holder.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grossman (US 5,342,328) in view of Szeles (EP 1,295,561 A1).

5. With regard to claim 12, Grossman et al disclose the invention substantially as claimed except for the removable cap includes a finger grip. Szeles, at c. 7 [0039] to c. 8, ll. 1-5 teaches the ability of a removable cap (12, 40) to include mating threads and ridges and protrusions to provide means for the user of the apparatus to attach the cap to the container as described at c. 9, [0043]. Therefore it would have been obvious to one having ordinary skill in the art at the time

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the invention was made to form the cap of Grossman including gripping portions as taught by Szeles since Szeles states at c. 3 to c. 4, [0021] that the advantage of forming a cap with this design is that the cap seals the container and at [0043] that the cap can be removed and reapplied by the user of the apparatus.

Double Patenting

16. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1 and 46 are rejected on the ground of nonstatutory double patenting over claim 1 of U. S. Patent No. 7,118,559 B2. Although the claims are not identical, both claim a fluid collection apparatus comprising a housing and holder connected together via first and second mating portion, however, the claims of the instant application further include a recitation of "a base disposed within said housing, said base being positionable on a support surface to support said holder and said housing in upstanding relation with respect to the support surface." and the patented claims do not state a recitation of a base. Although this feature is not disclosed or

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suggested by the prior art of record in combination with a fluid collection apparatus including an evacuated tube, the evacuated tube is only inferentially included in claims 1 and 46 and thus the tube is not required while the apparatus is not being used for fluid collection.

Allowable Subject Matter

17. Claims 43, 44, 45 and 48 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter: With respect to claims 43 and 44, the subject matter not found or suggested in the prior art is first and second connectors being male and female connectors. The prior art of record teaches integral parts having a poppet valve which is actuated by the needle of a syringe tip thereby establishing fluid communication. Claim 49 is allowable as being dependent from claim 48.

19. With respect to claims 45 and 48, the subject matter not found or suggested in the prior art is a base capable of supporting the housing, holder and tube thereby allowing the apparatus to be stood upright on a flat surface.

20. With respect to claim 50, the subject matter not found or suggested in the prior art is the mating portion being needleless and including connectors establishing fluid communication between the housing, holder and evacuated tube in combination with the housing being releasably coupled with the holder in sealing engagement by the connectors which establish fluid communication therebetween, and further in combination with a base capable of supporting the housing, holder and tube thereby allowing the apparatus to be stood upright on a flat surface in

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use conditions such that the amount of handling or hand manipulation required during collection of blood is reduced and thereby reducing the exposure of a physician or nurse to needle-sticks and reduced exposure to the blood being collected during use conditions. Claims 51 and 52 are allowable as being dependent from independent claim 50.

Response to Arguments

21. Applicant's arguments, see Remarks, filed 9 October 2007, with respect to the rejection(s) of claim(s) 1-12 and 43-46 under 35 USC 102 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of a different interpretation of the prior art, as detailed *supra*.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginger T. Chapman whose telephone number is (571)272-4934. The examiner can normally be reached on Monday through Friday 9:30 a.m. to 6:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on (571) 272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ginger Chapman
Examiner, Art Unit 3761
02/04/08



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER

